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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/479,145	01/07/2000	David E Weinstein	96700/595	2687

7590 06/19/2003

Amster Rothstein & Ebenstein
90 Park Avenue
New York, NY 10016

EXAMINER
HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/479,145	Weinstein
Examiner	**Art Unit**
Robert C. Hayes, Ph.D.	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) X Responsive to communication(s) filed on *Jul 12, 2001* .

2a) ☐ This action is **FINAL**. 2b) X This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) X Claim(s) *1, 3-5, 14, 16, 18, 19, 21, 23, 24, and 28* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) X Claim(s) *1, 3-5, 14, 16, 18, 19, 21, 23, 24, and 28* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____ .
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

Attachment(s)

1 X Notice of References Cited (PTO-892)

2 X Notice of Draftsperson's Patent Drawing Review (PTO-948)

3 X Information Disclosure Statement(s) (PTO-1449) Paper No(s). 11

5 Notice of Informal Patent Application (PTO-152)

6 Other: _____

DETAILED ACTION

Election/Restriction

1. Applicant's election without traverse of Group II (claims 1, 3-5, 7, 14, 16, 18-19, 21, 23-24 & 28 in Paper No. 11 is acknowledged.

Drawings

2. New formal drawings are required in this application because of the reasons provided on PTO form 948. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claim 5 is objected to because of the following informalities: a comma appears to be missing between the recitation of "insertion" and "rearrangement", based on the disclosure on page 12 (2nd *pp*) of the specification. Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 101

1. 35 U.S.C. 101 [illegible]

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 19, 21, 23 & 28 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. For example, the current recitation of "A host cell" encompasses a human organism (e.g., after gene therapy). It is suggested that amending the claims to "an isolated host cell" should obviate this rejection.

Claim Rejections - 35 U.S.C. § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-5, 7, 14, 18-19, 23-24 & 28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the isolated nucleic acid molecule of SEQ ID NO:2 encoding the human Opa1, does not reasonably provide enablement for any structurally and functionally uncharacterized polynucleotides, or biologically functional equivalents thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The name, "nucleic acid encoding Opa1", alone, or claims directed toward any random

thereof" or any biologically functional equivalent of any nucleic acid encoding any Opa1-related polypeptide or encoding any "nonfunctional Opa1 protein" (e.g., as defined on pages 10 & 12-13 of the specification) provides little or no structural characterization and little functional characteristics for knowing how to make and use the instant invention (i.e., as it especially relates to what metes and bounds define the open-ended definition for "having the biological activity of Opa1" in claims 7, 28, etc.). In particular, the specification fails to define what specific encoded amino acids are critical for any Opa1-related function, nor what nucleotide residues distinguish the nucleic acid of the instant invention from any nucleic acid encoding any different Opa1-related protein. Therefore, the skilled artisan would reasonably expect that random mutations to the nucleic acid encoding an Opa1 protein would result in an nucleic acid molecule encoding an inactive Opa1-related protein. For example, Rudinger states on page 3 that "it is impossible to attach a unique significance to any residue in a sequence. A given amino acid will not by any means have the same significance in different peptide sequences, or even in different positions of the same sequence". Rudinger then states on page 6 that "the significance of particular amino acid sequences for different aspects of biological activity cannot be predicted *a priori* but must be determined from case to case by painstaking experimental study". Thus, the lack of guidance provided in the specification as to what minimal structural requirements are necessary for an encoded Opa1-related protein's function would prevent the skilled artisan from determining

invention, because any such random modification/mutation manifested within an encoded Opa1-related polypeptide would be predicted to adversely affect the three-dimensional conformation of the encoded polypeptide, without requiring undue experimentation to determine otherwise.

6. Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

No required vector sequences are recited in claim 24 for expressing a nucleic acid that expresses Opa1, so that it can be subsequently "produced", and then "recovered"; thereby, constituting an incomplete method. In other words, introducing a DNA molecule alone with no operably linked expression sequences (e.g., as in an expression vector) would not reasonably transcribe nor "produce" anything.

Claim Rejections - 35 U.S.C. § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The second application must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the second application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

Therefore, because no description of any DNA molecule putatively encoding a OPA1 protein (i.e., SEQ ID NO:2) was disclosed in parent application 09/294,764, priority is granted only to the filing date of the instant application (i.e., 1/07/00).

Claims 1, 3-5, 7, 14, 16 & 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Birren et al. (Accession No. AC004148; submitted Feb. 16, 1998).

Birren et al. teach a human DNA molecule that "comprises" nucleotides 88-1680 of SEQ ID NO:2, which therefore, inherently encodes Opa1 (i.e., as it relates to claims 1 & 3). In that Birren's DNA contains additional sequences (i.e., one or two point mutations/insertions) and would hybridize at 100% of the nucleotide residues of SEQ ID NO:2, or contiguous fragments thereof, under high stringent conditions, the limitations of claims 4-5 & 7 are anticipated. In that Birren's DNA molecule is cloned in a BAC vector (designated clone HCIT524C5), the limitations of claims 14, 16 & 18 are met.

According to information provided by GenBank user services, sequences submitted to GenBank are processed and immediately placed into the public database unless the author(s) have requested that the sequences be withheld pending publication of an article. Processing

evidence to the contrary, that the cited GenBank record was available to the public shortly after its submission date and constitutes prior art under 35 U.S.C. § 102 (b).

It is noted that the above rejection is based in part upon a disclosure provided in a computer database record. Because the database was indexed so as to be available to the relevant part of the public, it is considered to be a U.S.C. § 102; see *In re Wyer*, 210 USPQ 790.

8. Claims 1, 4-5, 7, 14 & 18 are rejected under 35 U.S.C. 102(a) as being anticipated by Ansorge et al. (Accession No. AL050211; submitted May 15, 1999).

Ansorge et al. teach a human cDNA molecule that "comprises" nucleotides 880-1349 of SEQ ID NO:2, which therefore, inherently encodes a mutated/truncated Opa1 protein (i.e., as it relates to claims 1 & 4-5). In that Ansorge's DNA contains deleted sequences, and one or two point mutations, and would hybridize to 100% of the identical nucleotide residues within SEQ ID NO:2, or contiguous fragments thereof, under high stringent conditions, the limitations of claims 4-5 & 7 are anticipated. In that Ansorge's cDNA molecule is cloned in a pSport-1 vector (designated clone DKFZp586G1423), the limitations of claims 14 & 18 are met.

According to information provided by GenBank user services, sequences submitted to GenBank are processed and immediately placed into the public database unless the author(s) have requested that the sequences be withheld pending publication of an article. Processing typically takes from 2-3 days to a period of weeks. Sequences submitted to EMBL or DDBJ are transmitted to GenBank within 24 hours of their receipt. It therefore reasonably appears, absent evidence to the contrary, that the cited GenBank record was available to the public shortly after

It is noted that the above rejection is based in part upon a disclosure provided in a computer database record. Because the database was indexed so as to be available to the relevant part of the public, it is considered to be a U.S.C. § 102; see *In re Wyer*, 210 USPQ 790.

Claim Rejections - 35 U.S.C. § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-5, 7, 14, 16, 18-19, 21 & 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Birren et al., in view of Kim et al (1996).

Birren et al is as described above. However, Birren et al. do not specifically disclose a host cell transfected with their clone.

Kim et al. teach that BAC plasmids are transfected in *E. coli* host cells (e.g., pg. 213, 2nd col.; as it relates to claims 19, 21 & 23). However, Kim et al do not disclose a DNA encoding Opa-1.

It would have been obvious to one of ordinary skill in the art at the time of filing Applicant's invention to transfect Birren's clone into *E. coli* host cells in order to propagate this

10. Claims 1, 4-5, 7, 14, 18-19 & 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ansorge et al., in view of the 1990 GIBCO BRL catalogue and Sambrook et al. (1989).

Ansorge et al is as described above. However, Ansorge et al. do not specifically disclose a host cell transfected with their clone, nor a method of producing an Opa-1 protein.

The GIBCO BRL catalogue teach that pSport-1 plasmid vectors are multifunctional expression vectors for cloning into *E. coli* host cells (e.g., pg. 355; as it relates to claims 19, 21 & 23). However, the BRL catalogue does not disclose a DNA encoding Opa-1.

Sambrook et al. teach methods for making proteins in *E.coli* and recovering the proteins. However, Sambrook et al. do not teach a DNA encoding Opa-1 for subsequent use in their method.

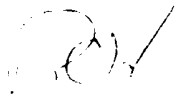
It would have been obvious to one of ordinary skill in the art at the time of filing Applicant's invention to transfect Ansorge's cDNA clone into *E. coli* host cells in order to propagate this cDNA molecule for further analysis, and to then produce and recover the encoded Opa1 protein using Sambook's method of producing and recovering proteins, because putative new proteins from human chromosome 17 may in the furture be useful to treat human disease states.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.
June 9, 2003